

“The examiner’s action will be complete as to all matters...” See MPEP 707.07 citing 37 CFR § 1.104. In light of the failure to comply with 37 CFR § 1.104, Applicants respectfully request that the finality of the previous Office Action be removed.

Removal of finality, and in the absence of an expedited allowance, a complete answer to all the following arguments is respectfully requested.

Status of the Application

Claims 8-16 are pending in the present application. Claims 14 and 15 are withdrawn from consideration as purportedly drawn to a non-elected invention. The Office Action rejects claims 8-12 under 35 U.S.C. § 102(b) as anticipated by four (4) separate references. The Office Action rejects claims 8-13 under 35 U.S.C. § 103(a) as rendered unpatentable based upon the same four (4) separate references in combination with an additional reference.

Support for the new claim can be found within the Example at page 11, lines 14-18 of the specification. No new matter is incorporated by this Amendment.

Restriction Requirement

Claims 14 and 15 are withdrawn from consideration as purportedly drawn to a non-elected invention.

Applicants respectfully traverse.

Claims 8-16 are pending in this application. The present claims are directed to an article of manufacture (Claims 8-9), a kit (Claim 10), and a pharmaceutical composition (Claims 11-16), all of which comprise HGF as an active agent.

Upon indication of allowable subject matter, Applicants respectfully request withdrawal of the Restriction and rejoinder of the claims. The claims under consideration and the claims withdrawn from consideration contain significantly parallel elements. Allowability in one set of

claims will demonstrate allowability in the remaining claims. Hence, withdrawal of the restriction requirement and rejoinder of the claims is appropriate.

Rejection under 35 U.S.C. §102(b)

Claims 8-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Rosen et al., Zarnegar et al., Grant et al., or Bussolino et al., all cited in the previous Office Action and in the IDS filed October 17, 2000.

Applicants respectfully traverse.

An anticipatory rejection is only appropriate when each and every element in the claims is expressly or inherently disclosed in the prior art. The disclosure of mere HGF in Rosen, Zarnegar, Grant, or Bussolino is not at issue. It is the lack of disclosure of the remaining claim elements in these references that gives rise to Applicants' arguments.

Claims 8 and 9 drawn to an article of manufacture comprising a container and a composition comprising an active agent within the container and the composition is effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease when administered intravenously, intraarterially, or via infusion. In addition, Claim 9 requires instructions for administering the HGF to a mammal to treat vascular insufficiency or limb ischemia secondary to arterial occlusive disease.

Claim 10 is directed to a kit comprising, in addition to the above-mentioned elements in Claims 8 and 9, a second container comprising a pharmaceutically-acceptable buffer. The remaining claims, Claims 11-16, are drawn to a pharmaceutical composition comprising a pharmaceutical carrier acceptable for intravenous, intraarterial or infusion administration.

Neither Rosen, Zarnegar, Grant, or Bussolino disclose a container containing the active agent, or a second container.

All the pending claims require as a necessary element, a composition effective for treating vascular insufficiency or limb ischemia secondary to arterial occlusive disease when administered intravenously, intraarterially, or via infusion. The composition, as emphasized, must be capable of imparting a treatment for the claim designated diseases when administered by the claimed routes. In all of the references, a relatively small amount of HGF is administered in carriers, such as matrigel or vinyl pelleting, that would be ineffective if utilized in a therapeutic method administered intravenously, intraarterially, or via infusion.

In the Office Action mailed April 5, 2002, reference is made to the Office Action mailed November 26, 2001 in which is stated, "Even the presence of written instructions for the intended use does not render the claims novel." Applicants respectfully request the authoritative basis for this statement. In addition, Applicants respectfully inquire how this statement regarding instructions also addresses the remaining elements emphasized above.

Applicant's respectfully inquire as to how the extensive recitation from MPEP § 2111.02 addresses the absences in the cited prior art to teach or suggest the above-noted elements of the claimed invention.

Rejection under 35 U.S.C. 103(a)

Claims 8-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rosen, Zarnegar, Grant, or Bussolino based on a combination with Godowski, U.S. Patent No. 5,316,921.

Applicants respectfully traverse.

Godowski does not cure the deficiencies noted above with respect to Rosen, Zarnegar, Grant, or Bussolino. There is no teaching or suggestion in any of these references, alone or in any combination, that addresses the required elements called for in Applicants claims.

Again, Applicant's respectfully inquire as to how the extensive recitation from MPEP § 2111.02 addresses the absences in the cited prior art to teach or suggest the above-noted elements of the claimed invention.

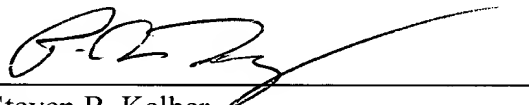
CONCLUSION

Applicants submit that the claimed invention is neither anticipated nor rendered unpatentable by Rosen, Zarnegar, Grant, or Bussolino, either alone or combined with Godowski. Reconsideration and withdrawal is respectfully requested.

Applicants assert that this application is now in condition for allowance and therefore request favorable consideration. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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